

Controlled Substance Guidelines for Missouri Practitioners



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BUREAU OF NARCOTICS AND DANGEROUS DRUGS (BNDD)
MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES

Dear Registrant:

The Missouri Bureau of Narcotics and Dangerous Drugs (BNDD) are publishing this guideline as a ready reference and review of the most common controlled substance laws. This guide does not address every single statute and regulation but it addresses the most common requirements and questions from practitioners.

The BNDD registers multiple types of individual practitioners who have different licensing boards or other governing agencies. This guide is prepared in chronological order to cover how to obtain a registration, registered locations, receiving drugs, proper storage, required record keeping, security, handling losses and issues pertaining to proper prescribing.

The abuse of prescription drugs is a serious social, criminal and health problem in the United States. As a medical practitioner, you share responsibility for preventing the diversion and abuse of prescription drugs. Treatment with controlled substances is always a balancing act; practitioners must do their best to safely and effectively treat their patients while at the same time avoid practices that could potentially foster drug misuse or abuse.

The BNDD publishes this guide and other educational materials available on the Bureau's website to assist practitioners from becoming a target for drug diversion. Additional educational publications, forms and a guide to preventing prescription fraud are available on the website of the Bureau at www.health.mo.gov/BNDD.

Respectfully,

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What Are Controlled Substances ?

A controlled substance is a drug or other substance that comes under the jurisdiction of the Federal Controlled Substances Act of 1970. Narcotics, depressants, stimulants, hallucinogens and anabolic steroids are regulated by the Controlled Substances Act (CSA) and are listed in one of five schedules.

Schedule I substances have a high potential for abuse and no accepted medical use in the U.S. Schedule II drugs also have a high abuse potential with a severe liability for psychic or physical dependence, but in general are substances that are approved by the FDA for a therapeutic use. Schedules III-V includes drugs with decreasing levels of abuse potential. Schedule IV drugs are predominantly benzodiazepines.

In the state of Missouri, the Comprehensive Drug Control Act of 1989, administered by the Bureau of Narcotics and Dangerous Drugs in the Missouri Department of Health and Senior Services, closely parallels federal law. The statutes are in Chapter 195 RSMo and the state regulations are in 19 CSR 30-1.00 through 1.078. In some instances, however, Missouri's law is more stringent and takes precedence over federal law. For example, in Missouri, narcotic-containing cough syrups and certain products that contain ephedrine are listed in Schedule IV and cannot be purchased without a prescription. In Missouri, drug products containing solid dosage forms of pseudoephedrine are Schedule V and must be signed for at the pharmacy counter. Legend drugs with pseudoephedrine that require prescriptions are not Schedule V.

Not All Drugs Are Controlled Substances:

Drugs fall into several different categories:

- Over-the-counter (OTC) for which no prescription is required;
- Legend prescription drugs that require a prescription; (*blood pressure, heart medications, birth control*)
- Specific prescription drugs that are deemed to be controlled substances and a prescription is required from a person with a BNDD and DEA registration. (*narcotics, steroids, amphetamines, benzodiazepines*)

Registrations are required to conduct any activities with controlled substances. If a practitioner does not have both state and federal controlled drug registrations, then they are prohibited from controlled drug activities. They may continue to treat patients with non-controlled drugs.

A List of Controlled Substances:

You may find a list of controlled substances in Missouri Statutes in Section 195.017, RSMo. These are listed by schedule.

For a more user-friendly listing of controlled substances, you may view a listing of controlled substances at the BNDD's website, www.health.mo.gov/BNDD. Under the link to publications, there is a list by Schedules and a list in alphabetical order.

Controlled Substance Registrations

For an individual practitioner to conduct any activities with controlled substances in Missouri, they must obtain registrations from both the Missouri Bureau of Narcotics and Dangerous Drugs (BNDD) first and then the federal Drug Enforcement Administration (DEA) secondly. A person must have their state registration first before applying for their federal registration.

A person may apply for a Missouri registration with the BNDD at the Bureau's website www.health.mo.gov/BNDD. An application may be submitted either electronically with a click-to-pay online system, or a person may print out the application and mail in a written application. Registrations are issued for a one year period and then they expire. Registrants must obtain a new registration annually. The Bureau will send registrants a reminder post card 60 days in advance of their expiration date to remind them that their registration expires in 60 days. If the Bureau does not receive a new application then the Bureau will mail out a second post card the week after expiration informing the former registrant they have expired.

Registration Locations: A Missouri registration may only be issued at a Missouri practice location where patient care occurs and controlled substance activities take place. This must be a physical street address and not a P.O. Box. The Bureau does not issue registrations at an out-of-state address or a location that only serves as a business address. Once a person has obtained a state registration then the federal DEA registration may be issued at the exact same address. The DEA verifies the addresses must match. A registration is issued at the principal practice location where the practitioner spends the majority of their time.

Changes in Addresses: Registrations are issued at a Missouri location where the practitioner spends the majority of their time. When the practitioner moves, changes addresses or changes the location of the majority of their practice, the practitioner must notify the BNDD and update their registration. A registrant may change their address for no fee at the BNDD website www.health.mo.gov/BNDD. The registrant has only 30 days to update their registration. If a practitioner changes addresses and does not notify the BNDD then their registration automatically terminates on the 31st day.

Situations Where No DEA Registration May Be Required: There are three circumstances where practitioners will only need a state BNDD registration and no federal DEA registration may be required:

1. Long-term care facilities are required to have a BNDD registration but do not have DEA numbers;
2. Physicians in a residency or training program must have a state BNDD registration but then may use the hospital's DEA registration with the hospital's permission. The hospital must assign a special suffix to the hospital DEA number to identify these physicians. Physicians in residency are limited by their limited license to treating patients of the hospital in which they are practicing.
3. A veterinarian must obtain a state BNDD registration and may work under the authority of another veterinarian who has a federal DEA number. This would allow the first veterinarian to administer and dispense controlled drugs within their employer's practice only. Since this veterinarian would not have their own federal DEA number, they are prohibited from issuing controlled substance prescriptions.

Registration Certificates: The BNDD stopped printing and mailing certificates in July 2010. Registrants may view, verify and print their own registration certificates online from our website www.health.mo.gov/BNDD.

Do I Need Multiple Registrations?

Most practitioners have only one registration. They can purchase, stock, administer, dispense and prescribe at their principal and registered location. They can travel all over Missouri and prescribe from any location.

Additional registrations are required if you:

1. Begin stocking and storing controlled substances at more than one location. There must be a separate registration at every separate location controlled drugs are stored and dispensed;
2. Perform other activities other than being a practitioner, such as becoming a manufacturer, distributor, researcher, analytical lab, importer or exporter.

Any questions regarding registrations should be directed to the BNDD at (573) 751-6321

Mid-Level Practitioner Registrations:

Beginning in 2011 the BNDD began registering advanced practice nurses and physicians' assistants. These practitioners must first obtain a certificate of authority from their respective licensing board, and then can submit applications to the BNDD for a state controlled drug registration. Although these practitioners do not purchase, stock and dispense controlled substances, they have prescriptive authority in Schedules 3, 4, and 5 and all laws pertaining to registrations, record keeping and prescribing apply.

Purchasing/Obtaining Controlled Substances:

When practitioners want controlled substances for administration and dispensing in their offices, the practitioners may only have controlled substances transferred to them by another authorized DEA registrant and proper transfer records of documentation must be maintained. There are strict requirements for what a stocking practitioner must do and there are specific laws about what practitioners cannot do to obtain controlled substances.

What you may do:

1. Purchase and obtain controlled substances from a pharmacy, wholesaler, distributor, or have drugs transferred to you by another DEA registrant. You should call the other registrant and share required information for documenting the drug transfer such the name, addresses and DEA numbers of the supplier and the receiver. A transfer form template is provided in the forms section of this booklet.

What you may never do:

1. No practitioner may issue a prescription to obtain office stock. Prescriptions are for patients only and must have a patient name. Never write a prescription for office stock. It is prohibited by law.
2. No practitioner may accept any portion of a patient's controlled substance prescription for any reason, unless you were the original practitioner who initially dispensed the drugs. This is by statute, Section 195.070.4, RSMo. If you dispensed drugs and the patient wants to return them, then you can take them back for destruction. If you were not the dispenser and the drugs came from a pharmacy or other practitioner, you may not take possession of the drugs.
3. Never store patients' controlled drugs for them in your practice.
4. Never store a patient's unused medications and use them for dispensing to other patients.

Continuous Record Keeping For Accountability

Controlled substances are documented and tracked from the day they are made until they are dispensed to a patient. Every time the drugs change hands there must be a documented paper trail.

Drugs are tracked from the manufacturer, to the distributor, then to the pharmacy or to the practitioner. Records must be maintained of the drug names, strengths, dosage forms and quantities you received and the dates you received them. You must also document the names, addresses and DEA numbers of other registrants you transfer with.

It is just similar to balancing a bank account. You must be able to document and account for every dosage unit you have received and every dosage unit you have administered or dispensed. You must be able to know what balance you should have on hand so that if any are missing it can be reported immediately.

As we go through activities with controlled substances in your practice we will cover the following types of record keeping requirements:

- | | | |
|-------------------------------|-----------------------------------|----------------------|
| 1. Purchasing/Receipt Records | 5. Administration/Dispensing logs | 9. Reporting losses |
| 2. Initial Inventory | 6. Prescription documentation | 10. How to audit |
| 3. Annual Inventory | 7. Faxing prescriptions | 11. Patient charting |
| 4. Transferring Drugs Out | 8. Disposal of unwanted drugs | |

Controlled Substance Receipt Records

Registrants must maintain a record of all controlled substances they receive. The receipt records must contain the following information:

- Name, address and DEA number of the supplier;
- Name, address and DEA number of the recipient;
- Drug name, strength, form and quantities received;
- The date the drugs were received.

All of this information must be maintained on file by the registrant and made available for inspection and copying. There are no exceptions for samples. All controlled substances must have records maintained.

Caution: If you choose to use a packing slip, invoice or billing record as your receipt record, you are responsible to make sure all of the information required above is documented on the records you maintain.

When you want to receive Schedule II drugs, you will execute a DEA Form 222 Order Form. You may also enroll in the DEA's electronic online Schedule 2 CSOS ordering system.

When you want to receive drugs in Schedule III—V, you may create a form or record of your own and no specific form is required. The record you create must have all of the required information. A transfer form template is available at the BNDD website at www.health.mo.gov/BNDD under the link to forms.

Receiving Schedule II Drugs Requires DEA Forms:

All transfers of Schedule II controlled substances between registrants require a DEA Form 222 Official Order Form. You may obtain these order forms from the DEA at www.deadiversion.usdoj.gov. They should be secured and any lost 222 forms must be reported to the DEA immediately. Registrants may also use the DEA's electronic online Schedule 2 CSOS system for obtaining controlled substances.

The registrant who is requesting the drugs starts the process. The purchaser fills out the form which has their name, address and DEA number. They list the drug name, strength, form and quantities desired. The name, address and DEA number of the supplier/distributor is documented. The form is sent to the supplier. The purchaser keeps the 3rd copy as a receipt record.

The supplier will receive the written form requesting the drugs. The order will be filled and shipped back to the purchaser. The purchaser must document their 3rd copy of the form to document what quantities they received and the dates of receipt. These forms must be maintained for two years.

Only the registrant whose name appears on the forms may sign and execute these order forms. If the registrant wishes to delegate the signing of these forms to another person, they may do so, however they must execute a power of attorney form. Power of attorney forms are available on the website of the BNDD at www.health.mo.gov/BNDD.

Receiving Schedule III – V Drugs

You are required to maintain a receipt record with all of the information previously mentioned above. You are responsible to make sure it is compliant. It is to your advantage to use the included form. If you document the form completely, both the supplier and receiver should keep a copy. It works as a “receipt” record for the receiver and then a “transfer out” record for the supplier.

Initial Inventory

On the very first day that you receive controlled substances for the first time, you must conduct an initial inventory on that day with your first arriving drug shipment. In case you want to perform an audit in the future to determine if drugs are missing, this initial audit would be your starting date. An initial inventory must document the following information:

- Registrant's name and DEA number;
- Date;
- Drug names, strengths, dosage forms and quantities;
- You must take the inventory at the opening or closing of business. You must document whether you took it at the opening or closing of business. You cannot take an inventory during business hours.
- If you have business that operates 24 hours, you must document the time of day;

An inventory template form is available at the Bureau's website www.health.mo.gov/BNDD under the link to forms.

This initial inventory should be documented and filed away. Do not write on it again.

Schedule II drugs should be inventoried and documented separately from drugs in Schedule III—V. Do not include other non-controlled drugs or items on these inventories.

Annual Inventory

Once a year you must perform an annual inventory of controlled substances. This inventory should be performed exactly like the inventory described above. If you are undergoing a records inspection you should be able to produce an annual inventory that is less than 12 months old.

This annual inventory should be documented and filed away. Do not write on it again.

Schedule II drugs should be inventoried and documented separately from drugs in Schedule III—V. Do not include other non-controlled drugs or items on these inventories.

This required annual inventory should be a separate document than an ongoing perpetual log you may have.

Storage of Controlled Substances

Individual practitioners must store controlled substances in a securely locked, substantially constructed cabinet or safe. Access to the storage area should be restricted to persons specifically authorized to handle the controlled substances. This includes restricting the number and accessibility of keys or passwords. It is not acceptable to have a lock where the key is sticking out of the lock or the key is located next to the cabinet. It is also not acceptable to have a safe with the combination written down near the safe so all can have access.

The safe or cabinet should remain locked at all times. It is not allowed to have it remain unlocked throughout the day while you are open for business.

If there are other practitioners in your building that have separate stocks of drugs then each practitioner must keep their individual drugs stored separately. Do not mix the drugs of multiple practitioners in one single safe or cabinet.

If the safe is small and portable it should be bolted to the floor or wall or placed in a locked closet.

If controlled substances are stored in a refrigerator then the refrigerator must have a lock.

Administering and Dispensing Controlled Substances

In this section we will cover the required record keeping for administering and dispensing controlled drugs, required packaging and labeling and proper actions by office staff.

Record Keeping—Administration/Dispensing Logs

Registrants must maintain a record of all controlled substances received, administered, dispensed, or otherwise disposed of. You must be able to document what patients have received drugs and how much and when. It is required that practitioners maintain a separate log of controlled substances administered and dispensed. You must document the date, patient name, patient address, drug name, strength, dosage form and quantity dispensed, and the name/initials of the person performing the dispensing. A dispensing log form is available on the BNDD website at www.health.mo.gov/BNDD under the link to forms.

This log must be maintained and filed separately from patients' charts. Although it is required to document all controlled drug activities in a patient's chart, the practitioner must also maintain this separate log. This log may be electronic as long as the electronic system is designed so the entries cannot be altered or deleted.

A Valuable Security Tool

Keeping this perpetual log provides a good security device to your practice. You can review the log and see what patients are receiving your drugs and how many and how often. All of the numbers should add up correctly and balance. If the count is off then you know that a drug has been diverted or someone dispensed without making a record. The log is also used to let you know when to order additional supplies. When someone wants to audit or inspect your dispensing you can present this log without pulling and reviewing all the patients' charts.

Packaging When Dispensing

When you dispense and give a patient a supply of drugs for future use, you must follow the same laws as a pharmacy. You must place the controlled substances in a child-proof container. Dispensing in envelopes or napkins or other devices violates the FDA's Poison Prevention Packaging Act of 1970. If you are dispensing samples, the FDA accepts the factory packaging for samples as being compliant containers. There is no need for you to place a factory sample into a child-proof bottle.

Required Labeling

When you dispense drugs you must apply required labeling to the packaging. You must provide a label that contains the following information:

- Name and address of the dispensing practitioner or pharmacy;
- Patient's name;
- If you're a pharmacy, name of the prescribing practitioner;
- If drugs are dispensed by a mid-level practitioner, the name of the collaborating physician must be documented;
- Drug name, strength, dosage form and quantity;
- Directions for administration;
- Date;
- If the practitioner is a veterinarian, the animal species and animal owner's name must be documented

The burden of proof is on a person to prove lawful possession of controlled drugs. If drugs are not labeled the person could be subject to arrest. In the past, patients arrested wrongfully have sued practitioners for not labeling medications as required and causing the patients to undergo an embarrassing arrest.

Required Warning Label or Caution Label

When a controlled substance is dispensed, the dispenser must affix a label or sticker that warns and cautions the patient that it is illegal to transfer these controlled substances to another person. This can be part of the major label or it may be a separate sticker.

Direct Supervision

When a registrant wants to have an employee dispense a controlled substance from their stock, the registrant must be present to provide direct supervision. When an animal is being euthanized a veterinarian is required to be present on the premises for supervision.

For Physicians Dispensing Non-Controlled Drugs

If you are a licensed physician you must also follow the regulations of the Missouri State Board of Registration for the Healing Arts. They have a non-pharmacy dispensing rule in State Regulation 20 CSR 2150-5.020 that includes the dispensing of all drugs and not just controlled substances.

Required Documentation in Patients' Charts

All controlled substance activities are required to be documented in a patient's chart. The controlled drug records in patients' charts are open for inspection and copying by BNDD. All controlled drug records must be maintained at the registered site and produced within 3 days upon request. All administrations, dispensing, prescriptions and refills must be documented with the date, drug, strength, form, quantities and refills.

Not having a chart not only violates the record keeping law but is consider failure to establish a legitimate practitioner-patient relationship and it is prescribing/administering/dispensing in the absence of good faith.

It is also a security violation. If prescriptions are not charted then practitioners would not know if a refill request was timely.

Please review the required record keeping requirements of your professional licensing authority to determine what other information must be documented. Pursuant to Section 195.375.5, RSMo, all controlled substance records are open for inspection by BNDD, DEA and local, state and federal law enforcement officials.

Transferring Drugs Out to Another Registrant

There may be a time when you need to transfer some drugs to another registrant. You may want to send drugs back to a distributor or maybe transfer drugs to a fellow practitioner who is running low in supplies. You must document the movement of the drugs with a transfer form. If it is a Schedule II drug, the receiving registrant would send you a DEA Form 222 Order Form. If the drugs are in Schedules III—V the two of you must document a transfer form. The documentation must include the names, address and DEA numbers of the supplier and receiver, as well as the date and the drug names, strengths, forms and quantities received. This document serves as a transfer record for the supplier and a receipt record for the receiver.

It is the responsibility of the supplier to always insure the person they are transferring drugs to is a BNDD and DEA registrant. The state registration of an individual practitioner can be verified at the BNDD website of www.health.mo.gov/BNDD. As an example, animal shelters do not currently have BNDD and DEA numbers.

Disposing of Unwanted Controlled Substances

There will be times when a practitioner wants to dispose of unwanted controlled substances. There are laws regarding how practitioners may dispose of unwanted controlled substances. This booklet is prepared for individual practitioners so this booklet does not cover disposal in licensed hospitals and long-term care facilities.

As a practitioner you must first ask yourself a question. "Why do I want to dispose of these medications?" There are two answers:

- A. The drugs have been contaminated by patient contact. It is a left-over injectable medicine in a syringe; or it was a tablet that fell out of a patient's hand or mouth. If this is the case, the drug may be destroyed by two employees in the practice. The drug must be destroyed beyond reclamation and documented as described below in the next section.
- B. The drugs have not been contaminated but they are out-dated, expired, or simply no longer wanted. In this case the drugs must be transferred to another registrant and they may not be destroyed by the practitioner. You may send them back to the distributor who supplied them if they will accept them. You may send them to a reverse distributor, which is a company that collects unwanted medications for destruction. There is a list of these reverse distributors at the BNDD website www.health.mo.gov/BNDD in the publication on how to dispose of drugs.

Documenting Controlled Substance Destruction

If you are administering and dispensing controlled substances then you should already be maintaining an administration and dispensing log to show the use of all controlled substances. The wastage and destruction of patient-contaminated controlled substances should be documented on this log to maintain an accurate balance.

The drug should be destroyed beyond reclamation. The destruction record should include the date, drug name, strength, form, and quantity destroyed. The reason for the destruction, the name person performing the destruction shall sign the log as well as the person witnessing the destruction.

How to Conduct an Audit of Controlled Substances

If you want to determine if any controlled substances are missing you must use all of your required records to conduct an audit. An example audit covering one year is shown below.

Annual inventory on 1-1-2011.....	200 tablets
<u>Drugs received 1-1-11 to 1-1-12.....</u>	<u>1,000 tablets</u>
Total You Are Responsible For	1,200 tablets
Tablets Administered/Dispensed 1-1-11 to 1-1-12.....	850 tablets
Tablets destroyed because of contamination.....	5 tablets
<u>Tablets returned to being outdated.....</u>	<u>100 tablets</u>
Total Doses Leaving the Practice	955 tablets

1,200 tablets minus 955 tablets = 245 tablets that should be in your safe.

Now you can see why all the records and dates are important.

Reporting Losses/Thefts of Controlled Substances

Registrants should always be able to tell if they have lost any controlled substances. They should have records in place so that an audit can be performed to determine if any drugs are missing. When reviewing the regulations, there are two types of losses described.

Insignificant Loss:

The drugs were not really “lost” and there was no crime or loss of accountability. This is when a compounding pharmacy has some liquid that sticks to the inside of a beaker or there is an amount of drug lost during a mixture or preparation. There was no theft or diversion. A tablet was dropped on the floor, stepped on and crushed and could not be picked up. When this happens, the drug was not truly “lost” because you know what happened to it. You must document this and what happened and it must be stapled to your annual inventory.

Lost or Stolen Controlled Substances:

These are cases where controlled substances were stolen, diverted or lost. This would include cases where drugs are missing and you are not sure where they went. These must be reported to the BNDD immediately upon discovery. You must submit a loss report form within 7 days. You must also submit a written loss report to the DEA. This is a DEA Form 106 for reporting lost or stolen drugs and you can obtain one at the DEA’s website www.deadiversion.usdoj.gov. In Missouri, a loss/theft report is required when any amount is lost, stolen, diverted outside the law, or when the registrant does not know what happened to the missing drug.

The BNDD loss/theft report form may be obtained at the BNDD website www.dhss.mo.gov/BNDD under the link to forms.

Documentation Required on Written Prescriptions

State and federal law requires that a prescription must have all of the information required documented on the face of the prescription in order for the prescription to be legal. Federal law states that both the prescriber and the pharmacy have a corresponding liability to make sure the information is documented. Both the prescriber and the pharmacy are liable. The prescriber has the primary responsibility. The following information is required for controlled substance purposes:

- The date the prescription was signed and issued;
- Patient's name and address;
- Name, address and DEA number of the prescriber;
- Drug name, strength, dosage form, quantity to be dispensed;
- Directions for administration or use;
- Signature of the prescriber- original ink if patient presents prescription at the pharmacy.
- If the prescription is for greater than a 30-day supply of a Schedule II drug, the prescriber must write the medical reason on the prescription. A diagnosis code number is not acceptable.
- If the practitioner does not want the prescription filled until a certain date the prescriber may write "Do not fill until _____" at the bottom of the prescription.
- Prescribers should indicate whether refills are authorized;
- Prescribers should indicate whether the drug must be dispensed as written or whether substitution is permitted.

Prescriptions Transmitted Verbally by Telephone

Prescriptions for Schedules III—V may be telephoned to a pharmacy. All of the information listed above is still required. The pharmacist must reduce it in writing and document the name of the person making the call and pharmacy employee receiving the call. Schedule II prescriptions may only be phoned in for emergencies where no other medical care is available. The prescriber must provide the pharmacy with an original prescription within 7 days. If no original prescription is presented as required, the pharmacy is mandated to report the prescriber to BNDD by law.

Only physicians may determine that the situation is an emergency and communicate this to a pharmacy. The physician must make the telephone call or sign the fax before it is transmitted. The communications of emergency Schedule 2 prescriptions cannot be delegated to another.

Faxing Controlled Substance Prescriptions

A prescription may be transmitted by fax machine however the document faxed must be a facsimile of a completely documented prescription that contains all of the required information. The prescription should be prepared with all of the required information. The practitioner must physically and manually sign it as required and then it may be faxed only after the prescriber has signed. The practitioner's signature cannot not be printed by another person and it may not be stamped and it may not say, "signature on file." A digitally scanned in electronic signature cannot be faxed. If the prescription is transmitted from a doctor's computer, via electronic prescribing, it may only be sent to a pharmacy's computer and cannot be sent to a fax machine. The DEA federal rule states that what starts electronic must stay electronic.

The majority of all faxed controlled substance prescriptions are for Schedules III, IV and V.

There are limitations for Schedule II prescriptions when sent by fax:

- A prescriber may fax a Schedule II prescription so the pharmacy can get it ready in advance. The pharmacy cannot dispense it until the patient presents the original prescription.
- The pharmacy may dispense a Schedule II prescription based solely on the faxed prescription under three conditions:
 1. The patient is in a long-term care facility and the prescription documents that fact;
 2. The patient is in a hospice program and the prescription documents that fact;
 3. The prescription is for a narcotic preparation to be administered by infusion, meaning parenteral, intravenous, intramuscular, subcutaneous or intra-spinal.

Prescribers File Faxed Prescriptions Separately

After the practitioner has signed the prescription, it may be faxed. After the prescription has been faxed, the person faxing the prescription should sign and date it to document it has been faxed. The faxed prescription must be placed in a separate file where all faxed controlled substance prescriptions are maintained in chronological order.

Although controlled substance prescriptions get documented in patients' charts, the prescriber must maintain a separate chronological file of faxed controlled prescriptions. This file of faxed prescriptions must be separate from patients' charts.

Electronic Prescribing Synopsis

The DEA has promulgated federal rules for the requirements pertaining to electronic prescribing. These rules may be viewed at the DEA website www.deadiversion.usdoj.gov. You will want to review federal rules 21 CFR 1306.08 and 21 CFR 1311.100 to 305. Here is a synopsis:

1. Electronic prescribing is a new option for practitioners. It is voluntary and not mandatory;
2. The rules are established by the DEA. Missouri does not have any additional or different rules. Practitioners may begin when they meet the federal requirements;
3. Prescriptions may be transmitted in all schedules, 2,3,4, and 5;
4. Medical software companies are working on applications and software packages that will enable electronic prescribing. These software packages and applications must undergo an audit and be reviewed before being authorized to begin. They should receive a certificate of authorization first and then they may provide their software product to practitioners. When practitioners are approached with the opportunity to purchase an electronic prescribing software, the practitioners should verify that the product they are purchasing has been DEA approved.
5. CAUTION: Do not prepare a controlled substance prescription and send it through your everyday email account. This is not allowed. Electronic prescribing may only occur within the DEA approved software system.
6. Electronic prescriptions will go from the prescriber's computer to a pharmacy computer where it will be archived. Electronic prescriptions cannot be sent to a pharmacy fax machine. Faxed prescriptions require a manual signature before faxing. The DEA rule states that what starts electronic must stay electronic. It cannot arrive at the pharmacy on paper.
7. Participating prescribers must under "identity proofing" before hitting the transmit-send button each time. It must be verified that it is the proper registered practitioner doing the prescribing. There are three approved ways to verify identity and the software system must use any two of them:
 - A. Something you know.....a password
 - B. Something you are.....a fingerprint or retina eye scan

- C. Something you have.....a token, USB device or smart card
8. Prescriptions may only be transmitted for one patient at a time.
 9. Prescriptions must be transmitted as soon as possible after identity proofing and the signature.
 10. Any prescription that is printed for a paper record, the document must be labeled, COPY ONLY—NOT VALID FOR DISPENSING.
 11. If the transmission fails—the practitioner may issue a written paper prescription and must document on it that this was initially sent electronically and failed.
 12. Pharmacies have controls on who may see and retrieve the data. Any changes or notations they make in the pharmacy must be electronic. Pharmacy records must be backed up daily and retained electronically.

What Can a Pharmacist Change on Prescriptions?

In the state of Missouri, pharmacies are required to follow what is informally called the NAME—NAME—NAME rule. Pharmacies cannot change the:

- NAME of the patient;
- NAME of the prescriber, or add a signature;
- NAME of the drug.

After contacting the prescriber and obtaining authorization, the pharmacy may make changes and document them on the prescription. The pharmacy should document the date and time of the call. The following changes may be made with the prescriber's permission:

- Date written;
- Patient address;
- Prescriber's address or phone number;
- Prescriber's DEA number;
- Directions for use;
- Quantity;
- Drug form or strength;
- Whether substitution is permitted;
- Refill information
- Verifying a faxed Schedule II drug is for a patient of an LTCF or hospice;
- Verifying a medical reason for Schedule II prescription supply that is greater than 30 days.

Multiple Schedule II Prescriptions

A practitioner may issue multiple prescriptions for Schedule II drugs on the same date. All prescriptions should be dated at the top on the date they signed and issued the prescriptions. Each prescription should have "Do not fill until ____" across the bottom. Although multiple prescriptions can be issued at once, the prescriber cannot exceed a 90-day supply of Schedule II drugs.

LTCF Issues For Practitioners & Pharmacies

Residents in long-term care facilities (LTCFs) obtain their medications through prescriptions. They do not obtain their medications from "orders." There is a legal difference between an "order" and a "prescription."

- Orders are verbal or written instructions from the practitioner to the nursing staff to obtain some of the drugs owned by the licensed facility and immediately administer them directly to the patient. In these cases, the facility owns the drugs and they are immediately administered.

- Prescriptions are only for retail pharmacies. Pursuant to law, only a retail pharmacy may dispense a prescription. If the prescriber is issuing a prescription that goes to a pharmacy, then all of the requirements of a prescription must be met and documented on the prescription.
- Pursuant to DEA guidelines, the physicians can sign agreements to have LTCF nurses act as agents.

CAUTION: Pharmacies cannot dispense a drug unless the prescription is completely and legally written. If a practitioner does not issue a complete prescription with all the information required, this prevents the patient from obtaining their medication timely.

LTCF Emergency Kits Do Not Require a Prescription:

The residents in LTCFs obtain their daily and routine medications through prescriptions. These prescriptions are considered to be the private property of the patient and these drugs are not owned by the facility.

The BNDD considers the drugs in the emergency kit to be in the possession of the LTCF and these emergency drugs are not patient owned. These drugs are maintained by the LTCF and they are the responsibility of the LTCF.

The DEA does not register LTCFs. According to a notice published by the DEA in the 1980s, the DEA stated they do not register and regulate LTCFs. LTCFs may stock drugs in an emergency kit without a DEA registration, as long as the LTCF is registered with a state agency such as Missouri BNDD. Since the Missouri BNDD registers LTCFs to stock drugs in an E-kit, the BNDD holds the LTCF responsible and sets forth the guidelines in State Regulation 19 CSR 1.052.

In the event of an emergency, the LTCF staff may contact the physician and obtain a verbal authorization to immediately administer from the emergency kit. This is an “order” for immediate administration from the facilities emergency stock. This is set forth in Missouri Regulation. In an emergency, once the physician has approved use of emergency drugs, the LTCF is not required to obtain additional authorization from a pharmacy. The drugs are in the possession of the LTCF and the LTCF is responsible.

There has been other information published by the DEA that they believe a LTCF should contact a pharmacy for prior permission during an emergency, however this is only a suggested guideline and it is not a federal law or regulation. The DEA is in the process of considering an entirely new type of registration for LTCFs that would allow them to obtain DEA registrations.

CHART OF PRESCRIBING LIMITATIONS

Prescription Characteristic	Limitation Schedule II	Limitation Schedule III and IV	Limitation Schedule V
Mode of issuing prescription	<ul style="list-style-type: none"> • Written mostly; • Verbal in an emergency by physician only • Faxed if injectable, To LTCF or hospice— doctor must manually sign; • Electronic as authorized by DEA 	<ul style="list-style-type: none"> • May be written or; • Orally phoned in; or • Faxed with manual signature; or • Electronic as authorized by DEA 	<ul style="list-style-type: none"> • May be written or; • Orally phoned in; or • Faxed with manual signature; or • Electronic as authorized by DEA
Refills	<ul style="list-style-type: none"> • No Refills Allowed; • Partial filling allowed for patients in LTCF or hospice 	Maximum of five within six months of issuing prescription	As authorized by the physician. Can be refilled PRN as prescriber allows for one year
Length of prescription validity	Six months	Six months	One year
Quantity limitations	<ul style="list-style-type: none"> • 30 days for most; • Rx for over 30 days requires medical reason; • Maximum is 90 day supply • Can write multiple & separate Rx with “Do Not fill until date” written on bottom. Can’t exceed 90 day supply 	90 days	90 days

What Constitutes a Legal & Legitimate Prescription

Federal and state regulations specify legitimate purposes for prescribing controlled substances:

- A prescription for a controlled substance is valid only if it is issued for a legitimate medical purpose by a practitioner acting in the usual course of their professional practice. If a prescription does not meet the legal standards under the Controlled Substances Act, then it does not meet the definition of “prescription” and it is considered an unlawful drug distribution.

Specific criteria should be met:

1. The prescriber must be properly registered.
 2. The patient must desire treatment for a legitimate illness or condition.
 3. A practitioner must establish a legitimate need through assessment, utilizing pertinent technical diagnostic modalities. There must be a legitimate practitioner/patient relationship.
 4. There must be reasonable correlations between the drugs prescribed and the patient's legitimate needs.
- The Intractable Pain Act, passed in 1995, provides guidelines for the treatment of chronic, intractable pain. This law was intended to clarify the parameters for treating chronic pain with controlled substances. The physician must document the diagnosis and treatment of chronic pain in the patient record and the use of controlled substances must be therapeutic in nature and manner utilized. Physicians may not prescribe or dispense controlled substances to a patient for chemical dependency unrelated to intractable pain or to a patient who the physician knows, or should know is using the medication in a non-therapeutic manner (unless they are approved and registered as a narcotic treatment program or federally approved office-based opioid treatment provider).

Practitioners may be subject to disciplinary action for nontherapeutic use of controlled substances, failing to keep accurate on-going treatment records, failing to keep complete and accurate controlled substance records, writing false or fictitious prescriptions, or prescribing controlled substances in a manner inconsistent with state or federal drug laws.

- Practitioners may not issue a prescription to obtain controlled substances for dispensing to patients. Practitioners can purchase controlled substance medications for stock from a drug distributor or pharmacy. A DEA form 222 must be used to obtain Schedule II controlled drugs. Each practitioner must maintain documentation as required under state and federal laws.
- Controlled drugs for a practitioner’s personal treatment must be prescribed by another appropriate practitioner, under the basis of an established practitioner/patient relationship. Practitioners are prohibited by law from prescribing or dispensing controlled drugs for their personal use except in a true medical emergency, such as a life-threatening condition or no emergency room being available.
- It is legal for practitioners to prescribe, dispense or administer controlled drugs to office staff or family members, but is not recommended. If the practitioner decides to treat family members or employees, the practitioner must do so under the auspices of a legitimate patient relationship and in “good faith”. This includes performing a proper evaluation, maintaining a chart, listing a diagnosis, plan of treatment and prognosis, and using the same documentation and care as with regular patients.
- “Internet Prescribing” – The Internet is primarily a communications tool that can be used to facilitate any type of business. The DEA issued a notice on April 27, 2001 in the Federal Register in reference to practitioners using the Internet as part of their business.

Some practitioners prescribe medications based on an on-line Questionnaire. Federal law requires that "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of their professional practice" ([21 CFR 1306.04\(a\)](#)). Every state separately imposes the same requirement under its laws. Under Federal and state law, for a practitioner to be acting in the usual course of professional practice, there must be a bona fide practitioner/patient relationship.

For purposes of state law, many state authorities, with the endorsement of medical societies, consider the existence of the following four elements as an indication that a legitimate practitioner/patient relationship has been established:

- A patient has a medical complaint;
- A medical history has been taken;
- A **physical examination** has been performed; and
- A legitimate clinical relationship exists between the medical complaint, the medical history, the physical examination, and the drug prescribed.

Completing a questionnaire that is then reviewed by a practitioner hired by an Internet pharmacy can not be considered the basis for a practitioner/patient relationship. A consumer can more easily provide false information in a questionnaire than in a face-to-face meeting with a practitioner. It is illegal to receive a prescription for a controlled substance without the establishment of a legitimate practitioner/patient relationship, and it is unlikely for such a relationship to be formed through Internet correspondence alone.

How to Prevent Diversion in Your Practice

Adherence to state and federal regulations goes a long way in protecting your practice from becoming a source of drug diversion and prescription drug abuse. The best practice is to have set policies and procedures and train your staff to follow them. The practitioner must provide supervision to see that the policies are enforced. Although many practitioners know laws and good practices they sometimes become too busy to supervise staff.

Suggestions for Practitioners on How to Protect their Practice and Patients:

1. Keep all prescription pads secure and not left out where people may obtain them to forge prescriptions.
2. Only the registered practitioner should be allowed to call in or place orders for new stocks of controlled substances.
3. If the practitioner is too busy and ordering new stock is delegated, only one employee should have the right to place orders. Do not let all staff members place orders.
4. When controlled drugs arrive in the practice, they should be opened, checked in, and added to inventory by at least two licensed professionals. Do not let one person do this alone. Do not let the same two people do it all the time.
5. The person who pays the bills should not be allowed to order drugs. The person who orders drugs should not be allowed to write checks. This prevents someone from ordering drugs and paying the bill without the practitioner's knowledge. The person who orders the drugs should communicate with the person who verifies what drugs the practice received. The receipt invoice should be given to a separate employee who pays the bills. **The receipt for drugs and bills should be reviewed by the practitioner.**
6. Only certain staff should be allowed to call in telephoned prescriptions to area pharmacies. The practitioner's staff may wish to designate a special "code word" or "secret password" with the pharmacy so the pharmacy knows the call is valid.

7. Use your continuing administration log as a perpetual inventory so you know how many dosage units have been dispensed and how many you have left on a daily basis.
8. As a practitioner, review the administration log to make sure you recognize the patient names and that no fictitious patient has been invented.
9. Only licensed professionals should have access to the locked drug cabinets.
10. Periodically, ask a local pharmacy for a print out of all the controlled substance prescriptions they have filled, that you issued. Look at the print out and make sure you recognize the names as your patients. Follow up on any names that seem strange or unfamiliar.
11. Set up a rotating self-inspection where on a monthly basis, the office manager or practitioner inspects the practice. Check the current stocks to make sure they are locked. Review the inventory and current balance. Review what has been ordered. Review what bills have been paid. Look at the administration log to make sure all the required information is recorded.
12. Make sure your controlled substances are inventoried at least once a year and recorded in your files. An inventory is required annually.
13. Set up a policy of random drug testing for employees.
14. If a practitioner chooses to treat their own family members or staff, they must keep charts and records on their family and staff just like any other patient. Allowing staff to take office medications on the job may lead to serious violations.
15. Before hiring a new employee, conduct an extensive background check by reviewing licensure discipline and running a criminal history check. Before employing any person with a criminal conviction for a drug offense who has access to controlled substances, the employer must first obtain a waiver. Drug related misdemeanors require a waiver from the BNDD and drug related felonies require a waiver from both the BNDD and the DEA.

Preventing Prescription Fraud & Drug Seeking Patients

The Bureau published a separate booklet titled Preventing Prescription Fraud. This is available at the Bureau's website www.health.mo.gov/BNDD under the link to publications. This booklet provides scams and tricks that professional patients use to mislead practitioners and also provides tips on how to deal with these patients, how to report fraud and what information can be shared without violating confidentiality laws.

Helpful Websites - Controlled Substance Information

BNDD.....www.health.mo.gov/BNDD

DEA.....www.deadiversion.usdoj.gov

State Boards.....To view the website of licensing boards in the Division of Professional Registration, visit the website at www.pr.mo.gov and then click on the licensing board of your choice. Many boards have their own educational materials and newsletters.

Caution

The purpose of this information is to educate and inform the practitioner of the regulations and statutes pertaining to controlled substances and make recommendations to assist the practitioner in protecting their practice and patients from diversion, drug abuse and misuse. It is not the intent to reduce or deny the use of controlled substances where medically indicated. Nothing in this booklet shall be construed as authorizing or permitting any person to do any act that is not authorized or permitted under federal or state laws. In addition, none of the policy and information in this booklet may be construed as authorizing or permitting any person to do any act that is not authorized, or refuse to meet any requirements imposed under the regulations published in the most recent publication of the Code of State Regulations or the Revised Statutes of Missouri.